

**REMARKS**

Claims 1-50 are pending. Claims 1-6, 19, and 20 are under examination. Claims 7-18 and 21-50 have been canceled as drawn to a non-elected invention. Claims 2 and 20 have been canceled without prejudice. Claims 1, 3-6, and 19 have been amended. Claims 51-54 have been added. Accordingly, claims 1, 3-6, 19, and 51-54 are pending.

Specifically, claim 1 has been amended to incorporate the limitations of claim 2 and to specify that the oscillating element is capable of generating ultrasound energy at a frequency of between 100 kHz and 4 MHz. Support for the amendment of claim 1 can be found in the specification and the claims as originally filed. In particular, support for the amendment of claim 1 can be found in the specification, for example, at page 17, lines 9-13.

Claims 3-6 have been amended to specify their dependency from claims 1 and 51.

New claim 51 is drawn to the device described in originally filed claim 1 further comprising a pressure-sensitive switch. Support for new claim 51 can be found in the specification and the claims as originally filed, in particular, for example, at page 8, line 35 through page 9, line 1.

New claims 52 and 53 are drawn to the device described in originally filed claim 1 wherein the therapeutic agents are selected from the group consisting of papaverine, prostaglandin E1 (PGE 1), minoxidil, prostaglandins, organic nitrites, inhibitors of the renin-angiotensin system, inducible Nitric Oxide Synthase (iNOS) agents, and phosphodiesterase type 5 inhibitors, e.g., sildenafil and alprostadil. Support for new claims 52 and 53 can be found in the specification and the claims as originally filed, in particular, for example, at page 3, lines 30-34.

New claim 54 is drawn to the device described in originally filed claim 1 wherein the therapeutic agents are selected from the group consisting of minoxidil, finasteride, fabao-101, cyproterone acetate, ethinyl estradiol, aldactone, and spironolactone. Support for new claim 54 can be found in the specification and the claims as originally filed, in particular, for example, at page 8, lines 1-6.

The foregoing claim amendments and/or cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done

solely to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s). No new matter has been added.

### ***Objection to the Drawings***

The drawings are objected to "because on page 15 line 12, reference numeral '27' is not shown in figure 9; on page 16 line 7, reference numerals '60' and '20c' are not shown in the drawings; Figure 10 does not have a traversal cut line to show what is shown in Figure 11."

Applicants defer correction of the drawings until the indication of allowable subject matter.

### ***Objection to the Specification***

The specification is objected to "as failing to provide proper antecedent basis for the claimed subject matter." In particular, the Examiner states that "[c]orrection of the following is required: the device comprising a battery as set forth in claim 20 for the elected species."

Applicants traverse this rejection. However, in the interest of expediting prosecution, claim 20 has been canceled. Therefore, this rejection is moot.

### ***Rejection of Claims 1-6 and 20 under 35 U.S.C §102(e)***

Claims 1-6 and 20 are rejected under 35 U.S.C. §102(e) "as being anticipated by Bock (5,618,275)." Specifically, the Examiner states that "Bock discloses an ultrasonic device comprising an applicator 1, 2, 3, and an ultrasound transducer 13."

Claims 2 and 20 have been canceled without prejudice. Therefore this rejection is moot with regard to claims 2 and 20. To the extent this rejection applies to amended claims 1, 3-6 and new claim 51, Applicants traverse.

Claim 1 and dependent claims 3-6, as amended, are drawn to a device for transdermal administration of topical therapeutic agents, comprising an applicator for applying an effective amount of a therapeutic agent to a tissue surface of a subject, and an ultrasound transducer, operatively coupled to the applicator, for providing ultrasound

energy to the tissue surface at least one predetermined frequency to promote transdermal absorption of the drug through the tissue of the subject, wherein the ultrasound transducer further comprises at least one oscillating element capable of generating ultrasound energy at a frequency of *between 100 kHz and 4 MHz*. Bock fails to teach or suggest the claimed device.

Bock discloses a *low frequency* ultrasonic device. In particular, Bock shows an ultrasonic device which generates ultrasonic waves in the frequency range of 15,000 to 25,000 Hertz (col. 4, ls. 27-29). Bock fails to teach or suggest the claimed device which includes a high frequency range of between 100 kHz and 4 MHz. In fact, Bock teaches away from using the frequency range encompassed by the claimed invention. Based on at least the foregoing, claims 1, 3-6, and 19 are novel in view of Bock.

Furthermore, new claim 51 is drawn to the device of original claim 1 further comprising a pressure-sensitive switch. Bock fails to teach or suggest an ultrasonic device which includes a pressure-sensitive switch. Accordingly, claim 51 is also novel in view of Bock.

Similarly, new claims 52-54 are drawn to the device of original claim 1 wherein the therapeutic agents are various therapeutants for treating erectile dysfunction and hair loss. Bock fails to teach or suggest the transdermal application of such drugs. Accordingly, claims 52-54 is also novel in view of Bock.

#### ***Rejection of Claims 1-6 and 20 under 35 U.S.C §102(e)***

Claims 1, 19, and 20 are rejected under 35 U.S.C. §102(e) "as being anticipated by Ogden (5,656,016)." Specifically, the Examiner states that "Ogden discloses a drug delivery device comprising an applicator 12, an ultrasound transducer and a detector for monitoring feedback signals from the transducer (col. 4, lines 17-23)."

Claim 20 has been canceled without prejudice. Therefore this rejection is moot with regard to claim 20.

Furthermore, claim 1 has been amended to incorporate the limitations of claim 2 to which this rejection does not apply. Therefore, this rejection is moot with regard to claim 1.

To the extent this rejection applies new claim 51, Applicants traverse. New claim 51 is drawn to the device of original claim 1 further comprising a pressure-sensitive switch. Ogden fails to teach or suggest an ultrasonic device which includes a pressure-sensitive switch. Accordingly, claim 51 is novel in view of Ogden.

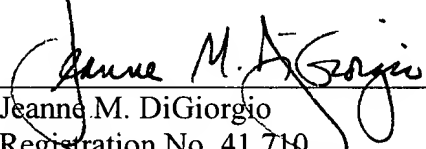
To the extent this rejection applies new claims 52-54, Applicants traverse. New claims 52-54 are drawn to the device of original claim 1 wherein the therapeutic agents are various therapeutants for treating erectile dysfunction and hair loss. Ogden fails to teach or suggest the transdermal application of such drugs. Accordingly, claims 52-54 are novel in view of Ogden.

### CONCLUSION

In view of the amendments and remarks set forth above, it is respectfully submitted that the pending claims are in condition for allowance. If there are any remaining issues or the Examiner believes that a telephone conversation with Applicants' Attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

Respectfully submitted,

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